

**MEETING SUMMARY**  
**of the**  
**NATIONAL BIODEFENSE SCIENCE BOARD**  
**A FEDERAL ADVISORY COMMITTEE FOR THE**  
**OFFICE OF THE SECRETARY OF THE**  
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Teleconference**  
**October 14, 2008**  
**Washington, DC 20201**  
**10:00 AM to 11:00 AM EST**

**VOTING MEMBERS PRESENT**

Patricia Quinlisk, M.D., M.P.H., Chair NBSB  
Ruth L. Berkelman, M.D.  
Stephen V. Cantrill, M.D.  
Roberta Carlin, M.S., J.D.  
Albert J. Di Rienzo  
Kenneth L. Dretchen, Ph.D.  
John D. Grabenstein, R.Ph., Ph.D.  
James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A.  
Thomas J. MacVittie, Ph.D.  
John S. Parker, Major General (Retired), M.D.  
Andrew T. Pavia, M.D.  
Eric A. Rose, M.D.  
Patrick J. Scannon, M.D., Ph.D.

**EX OFFICIO MEMBERS PRESENT (or designee)**

Diane Berry, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security  
Michelle M. Colby, D.V.M., M.S., Office of Science and Technology Policy, Executive  
Office of the President (Seth Cohen, designee)  
Rosemary Hart, J.D., Office of Legal Counsel, U.S. Department of Justice  
Peter Jutro, Ph.D., National Homeland Security Research Center, U.S. Environmental  
Protection Agency  
Carol D. Linden, Ph.D., Biomedical Advanced Research and Development Authority,  
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of  
Health and Human Services  
Boris D. Lushniak, M.D., M.P.H., Rear Admiral/Assistant Surgeon General, Office of the  
Commissioner, Food and Drug Administration, U.S. Department of Health and  
Human Services  
Patricia A. Milligan, R.Ph., C.H.P., U.S. Nuclear Regulatory Commission

COL John P. Skvorak, D.V.M., Ph.D., U.S. Army Medical Research Institute for Infectious Diseases, U.S. Department of Defense  
Richard S. Williams, M.D., Office of the Chief Health and Medical Officer, National Aeronautics and Space Administration (Vince Michaud, designee)  
Patricia R. Worthington, Ph.D., Office of Health and Safety, U.S. Department of Energy (Bonnie Richter, designee)

### **EX OFFICIO MEMBERS NOT PRESENT**

Joseph Anelli, D.V.M., Animal and Plant Health Inspection Service, U.S. Department of Agriculture  
Hugh Auchincloss, M.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services  
Richard E. Besser, M.D., Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services  
Lawrence Deyton, M.D., M.S.P.H., Chief Public Health and Environmental Hazards, U.S. Department of Veterans Affairs  
Bruce Gellin, M.D., M.P.H., National Vaccine Program Office, Office of the Secretary, Office of Public Health and Science, U.S. Department of Health and Human Services  
Lawrence (Larry) D. Kerr, Ph.D., National Counterproliferation Center, Office of the Director of National Intelligence  
Claudia A McMurray, Ph.D., Environmental and Scientific Affairs, U.S. Department of State  
Carter Mecher, M.D., Homeland Security Council, Executive Office of the President  
Timothy R. Petty, Deputy Assistant Secretary for Water and Science, U.S. Department of the Interior  
Frank Scioli, Ph.D., Division of Social and Economic Sciences, National Science Foundation

### **STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD**

Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director  
Erin Fults, Technical Writer  
Donald Malinowski, M.S., Program Analyst  
David Noll, Ph.D., Science Policy Fellow  
Amanda Richardson, Ph.D., Science Policy Fellow  
Andrew Rickles, Program Analyst  
MacKenzie Robertson, Program Analyst  
Carolyn Stevens, Executive Assistant  
Brook Stone, M.F.S., LT JG, U.S.P.H.S., Program Analyst

### **BACKGROUND**

Ruth L. Berkelman, M.D., co-chair of the Personal Preparedness Working Group with Andrew T. Pavia, M.D., explained that the National Biodefense Science Board (NBSB) formed the Working Group in response to information presented at the Board's June 2008 meeting on specific efforts to promote personal preparedness. Those efforts included, 1) exploring home stockpiles of antibiotics to be used in case of an anthrax

attack, and 2) guidance documents from the U.S. Department of Health and Human Services (HHS) to the public and health care providers on prescribing antibiotics so that individuals may maintain their own home stockpiles.

Immediately following the June meeting, and again in August, the Board wrote letters to the Secretary of HHS describing its discomfort with the pace at which promotion of home stockpiling through use of individual prescriptions appeared to be proceeding. In its letters, the Board recommended addressing concerns of government officials, clinicians, and the community and obtaining answers to specific scientific questions before moving too abruptly into promoting home stockpiling.

If submitted, the U.S. Food and Drug Administration (FDA) can review a new drug application (NDA) for a MedKit that, 1) contains antibiotics against anthrax and 2) would be disseminated to households as a new medical product. New or modified indications, usage, labeling, or distribution of a previously approved product (i.e., antibiotics to treat anthrax) requires FDA approval through the NDA process. The Working Group is seeking more information from HHS about existing efforts to disseminate MedKits or other countermeasures, both domestically and internationally, and about the evaluation components of planned pilot programs that involve home stockpiling of antibiotics.

## **PROPOSED RECOMMENDATIONS**

### **RECOMMENDATION #1**

High-quality information can and should be obtained from an operational evaluation during the pre-positioning of antibiotic countermeasure programs. Collecting quantitative and qualitative information would enhance rather than detract from the operational aspects of those programs. Moreover, it would provide complementary and supportive data to that gathered in planned studies that make up the core of an NDA package for purpose-built antibiotic stockpiles. This recommendation should be considered for the two separate activities specified below.

- a. Regarding the planned implementation of the Cities Readiness Initiative (CRI) Postal Module in Minnesota, we believe that there is extensive experience and expertise among the epidemiologists at the Minnesota Department of Health as well as at the Centers for Disease Control and Prevention for this activity.
- b. Regarding the potential pre-positioning of antibiotics for the January 2009 Inaugural Capitol Region program, we believe that there is extensive experience and expertise among the epidemiologists within the National Capitol region, as well as at the Centers for Disease Control and Prevention for this activity.

## **DISCUSSION**

Matthew Minson, M.D., Office of the Assistant Secretary for Preparedness and Response (ASPR), HHS, clarified that the Emergency Use Authorization (EUA) for the Minnesota CRI pilot project differs from the EUA for the National Capitol Region program that would allow first responders to have a personal cache or stockpile of antibiotics to treat anthrax. The EUA for the Minnesota project applies to the U.S. Postal Service workers

who volunteer for the project and their families; the EUA for the National Capitol region would apply only to adult first responders. Aubrey Miller, M.D., M.P.H., Office of the Commissioner, Office of Counterterrorism and Emerging Threats, FDA, HHS, said that the EUA for the Minnesota CRI project specifies a number of different conditions including the ongoing collection of data regarding adverse health effects and the collection of information every six months regarding the ability of recipients to store and use the product correctly.

## **RECOMMENDATION #2**

We recommend that operational and qualitative research be conducted in order to better understand what issues and triggers drive individual decisions to participate in personal preparedness activities and their adherence to instructions on proper storage and use of individual antibiotic caches. Lessons can be learned from disaster preparedness in high risk areas for storms (high probability, moderate impact) and earthquakes (low probability but possibly catastrophic impact) where personal preparedness has been emphasized for many years.

## **DISCUSSION**

Dr. Pavia explained that before recommendations are made that encourage individuals to consider home stockpiling of antibiotics, more understanding is needed of whether and why people follow more general personal preparedness advice.

## **RECOMMENDATION #3**

A draft HHS document, "Personal Preparedness for an Anthrax Emergency: Benefits and Risks of Home Storage of Antibiotic Drugs: Questions and Answers," was provided to the NBSB members at the August 11, 2008, teleconference. Pending review by the Personal Preparedness Working Group of the NBSB, we recommend that this draft document be considered for pilot testing in programs such as the CRI Postal Module in Minnesota or any other separate program, such as the January 2009 Inaugural Capitol Region program.

## **ACTION ITEM**

The Personal Preparedness Working Group will review the "Questions and Answers" document and provide comments that will be shared with the pilot projects described or other programs as appropriate.

## **RECOMMENDATION**

The three recommendations of the Personal Preparedness Working Group were accepted as written by unanimous vote of the Board. The Board will submit the recommendations to the Secretary of HHS for consideration.

## **NEXT STEPS**

- The Board will request a response from HHS leadership regarding its initial recommendations on personal preparedness.
- The Board will request that HHS provide updates on findings from the pilot projects and programs with a personal preparedness component.
- NBSB staff will solicit input via ex officio members and others on where to obtain information about the factors that trigger individual decision-making and preparedness, whether from formal research or informal program evaluations. Such information will be included on future agendas of the Personal Preparedness Working Group.
- Dr. Miller will provide the Board a copy of the EUA for the Minnesota CRI project so that members can evaluate how the project is required to collect information.
- James J. James, Brigadier General (Retired), M.D., Dr.P.H., M.H.A., will provide information gathered by the American Medical Association on various population subgroups that were affected by Hurricane Katrina.
- Roberta Carlin, M.S., J.D., will provide information gathered from people with disabilities regarding preparedness.
- The Board will request that an appropriate HHS agency, such as FDA or the Office of the Assistant Secretary for Preparedness and Response, determine whether the recommendation for broader program evaluation is consistent with the requirements and conditions of the EUAs granted.

## **CONCLUSION**

No public comments were offered. The next in-person, public meeting of NBSB will take place November 18–19, 2008, at the Sheraton National hotel in Arlington, VA. Details will be available on the website <http://www.hhs.gov/aspr/omsph/nbsb/>.